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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,050	10/30/2003	Orhan Soykan	P-10120.00	1185

7590

07/05/2006

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EXAMINER

WINAKUR, ERIC FRANK

ART UNIT	PAPER NUMBER
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3768

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/698,050	<b>Applicant(s)</b> SOYKAN ET AL.	
	<b>Examiner</b> Eric F. Winakur	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) 22-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 and 33-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear how the limitation of claim 10 can be met, as independent claim 1 sets forth that the analyte detector is for troponin, and it is unclear how the detected analyte can be both troponin and one of the analytes set forth in claim 10.

#### ***Claim Rejections - 35 USC § 101***

4. Claims 1, 2, 4 - 10, and 18 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. With regard to claims 1, 2, and 4 - 10, claim 1 appears to be directed to processing data to determine physiological information rather than a practical application involving the physiological information. The claim does not result in a physical transformation nor does it appear to provide a useful, concrete and tangible result. Specifically, it does not appear to produce a tangible result because merely detecting a change in a concentration is nothing more than a computation within a processor. The claimed invention fails to use or make available for use the result of the detecting to enable its functionality and usefulness to

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be realized. Additionally, the asserted practical application in the specification is for generating an alarm or controlling a therapy device based upon the results. The practical application is not explicitly recited in the claims nor does it flow inherently therefrom. Therefore, claim 1 appears to be non-statutory.

In addition, dependent claims 2, and 4 - 10, while reciting further limitations, fail to explicitly or inherently recite the practical application.

5. With regard to claim 18, the claim improperly includes a living subject as part of the claimed subject matter by reciting "are implanted in the body". The claim should be amended to recite "are adapted to be implanted in the body" to avoid this problem.

***Claim Rejections - 35 USC § 103***

6. Claims 1 - 8, 10, 11, 13 - 16, 19 - 21, and 33 - 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. (USPN 6,040,194 - previously cited) in view of Wicks et al. Chick et al. teach a method and arrangement for detecting an analyte in the human body comprising placing an analyte detector with two fluorescent dyes within the body, illuminating the detector, and measuring the analyte concentration based upon the ratio of energy emitted by the two dyes as a result of fluorescent resonant energy transfer (FRET) between them (col. 2, line 31 - col. 6, line 44). Further, a drug delivery system in communication with the analyte detector may be implanted in the body such that a feedback loop is established wherein a prescribed amount of drug is released when the measured analyte concentration exceeds a certain threshold (col. 6, lines 1-5). The illuminating energy is visible light at a wavelength of 472 nm (col. 11, lines 36-47) and the analyte measured may be a protein in the blood (the level of which

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may vary under certain physiological states) or an antigen or a narcotic such as cocaine or heroin (col. 5, lines 15-50). Thus, Chick et al. teach all of the features of the invention except that the sensed protein is troponin. However, Wicks et al. teach that troponin I is a protein that is a marker for cardiac damage (column 1, lines 24 - 41). It would have been obvious to one of ordinary skill in the art at the time of the invention to implement Chick et al. with sensitivity for troponin, since Chick et al. teach that their method and arrangement are suitable for detecting proteins in the blood that are indicative of physiological states and Wicks et al. teach that troponin I is a blood protein that is a marker for cardiac damage.

7. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Wicks et al. as applied to claim 1 above, and further in view of Khaw et al. The combination of Chick et al. and Wicks et al. teaches all of the features of the claimed invention except that the analyte is cardiac troponin-T antigen. However, Khaw et al. teach that troponin I and T are alternate equivalents for sensing heart attack related events (paragraphs [0002] and [0011]). Chick et al. teach that the antigen is used to detect a protein (column 9, line 59 - column 12). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination of Chick et al. and Wicks et al. to sense troponin T, since Khaw et al. teach that this is an alternate equivalent expedient and it has generally been held to be within the skill level of the art to substitute alternate equivalent expedients.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Wicks et al. as applied to claim 11 above, and further in view of Kwon

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(previously cited). The combination teaches all of the features of the claimed invention except for the particularly claimed fluorescent dyes. Kwon teaches monitoring analyte concentrations in the body using FRET, wherein one of the dyes which may be used is tetramethylrhodamine isothiocyanate. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use with the FRET system disclosed by the combination with the fluorescent dye tetramethylrhodamine isothiocyanate, since Kwon teaches that this dye allows for effective FRET analyte concentration measurements.

9. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Wicks et al. as applied to claim 11 above, and further in view of Rao et al. (previously cited). The combination teaches all of the features of the claimed invention except that there is an alert module. Rao et al. teach an alternate FRET system that includes an alert module notify a subject of changes in concentration (see Figure 9 and the description thereof). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to include an alert module, as taught by Rao et al., since this allows a subject to be notified of changing concentrations.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chick et al. and Wicks et al. as applied to claim 11 above, and further in view of Van Antwerp et al. The combination teaches an implantable sensor with transdermal determination of analyte concentrations (column 6, lines 6 - 34; column 16, line 23 - column 17, line 32). Van Antwerp et al. (Figure 6 and the description thereof) teach an alternate arrangement that includes completely implantable emitter, detector, and sensing

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elements. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the combination to use a completely implantable arrangement, as taught by Van Antwerp et al., since this is merely an alternate equivalent expedient.

### ***Response to Arguments***

11. Applicant's arguments with respect to claims 1 - 21 and 33 - 37 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur  
Primary Examiner  
Art Unit 3768